

Remarks

The IDS problems pointed out on page 2 of the office action are corrected by provision of the missing references herewith.

Applicants disagree with the drawing observations on pages 3 and 4 of the office action because the Legend of the Figure states: "Amino acid sequence of the antibody L19" and the figure itself states "VH". Consequently, it is clear from the figure itself that it is the amino acid sequence of the VH region of antibody L19 which is presented. Nevertheless, in order to render this issue moot, Figure 6 is being deleted in its entirety and the subsequent figures have been renumbered accordingly and indicated at the top as being a "replacement sheet." The specification has been amended accordingly.

Applicants appreciate the examiner's observations on page 3 regarding the heading to the canceled Table. Applicants agree the amendment made no sense and properly was not entered. The inadvertent error in amending pages 23 and 24 of the specification is being corrected herewith. See page 4 of the office action. A consistent sequence listing will be filed which deletes the canceled sequences. As shown below, no new matter is involved in deletion of the sequences originally set forth. Also, appreciation is expressed for the examiner's observations regarding claims 24 and 28.

In the last paragraph on page 13, the examiner has "noted that Applicant has obscured this issue by deleting the material describing the L19 antibody as original [sic] filed." Whereas it is true that applicants have deleted the material mentioned by the examiner, it is not true that this was done for purposes of obscuring anything. In fact, it was applicants' view during a telephonic interview that changes in the originally disclosed sequences were not really necessary since the public was given full notice by applicant of the errors in the file history. It is the recollection of the undersigned that it was the PTO which recommended correction of all erroneous information with a statement to the effect that no patent was to issue from this application with any errors in it, the errors of course being those disclosed by applicants. If the undersigned has misunderstood the PTO's position or if the PTO has changed its mind, applicants are fully happy to comply with whatever the current wish of the PTO is. Currently, applicants have attempted to provide a specification free of all errors in accordance with the understanding of the undersigned of the

PTO's wishes.

The examiner is also thanked for pointing out the oversight regarding the necessary statements for the deposit. Accordingly, applicants hereby state:

1. Deposit PTA-9529, made on September 30, 2008, in the American Type Culture Collection, Manassas, VA, has been accepted by such depository under the provisions of the Budapest Treaty; and

2. All restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application.

Consequently, it is now clear that the technical requirements for a proper deposit are completed.

The foregoing claim amendments limit the encompassed subject matter by way of a definition which is based on the DNA sequences contained in the deposited biological material. As demonstrated below, such a claim referring to sequence information contained in a deposit, which sequence is not recited in the specification per se, has been explicitly sanctioned by the Federal Circuit (*Enzo Biochem. Inc. v. Gen-Probe Inc.* 323 F.3d 956 (Fed. Cir. 2002)), even when the deposit is made after the effective filing date of an application (*In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985)). This is demonstrated below taking into account fully the points raised in the office action.

Relevant Law

Does U.S. law permit an applicant to deposit a biological material for purposes of enabling the preparation of such biological material and for purposes of providing a written description of such biological material, even where the patent specification otherwise does not provide enablement or written description?

The Federal Circuit has made very clear that deposits of biological material can be used to provide full satisfaction of the enablement and the written description requirements.

While deposit in a public depository most often has pertained to satisfaction of the enablement requirement, we have concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material. (emphasis added) (*Enzo*)

* * *

We therefore agree with *Enzo* that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement. (*Enzo*)

Can such a deposit be made after the filing date of an application and can the resultant new deposit information (depository details and accession number) be added to a patent application without new matter being involved?

The *Lundak* court provides clear “Yes” answers to both aspects of this question.

The requirements of PTO access to a sample of *Lundak*’s cell line during pendency, and public access after grant, were met by *Lundak*’s procedures. *Lundak*’s deposit with the ATCC, which was made after filing but prior to issuance of his patent, and which is referred to in his specification, meets the statutory requirements. (*Lundak*)

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An accession number and deposit date add nothing to the written description of the invention. They do not enlarge or limit the disclosure. This is not the shape of new matter against which section 132 was designed to guard.

Constructive reduction to practice does not turn on the question of who has possession of a sample, and thus it does not turn on the inclusion or absence, in the specification as filed, of the name and address of who will have possession of the sample on grant of the patent.

We conclude that *Lundak*’s specification as filed met the requirements of constructive reduction to practice, and that the insertion of depository data after filing is not new matter under 35 U.S.C. § 132. (*Lundak*)

Conclusion: As a result, the Federal Circuit has made clear that the deposit made in this application and the insertion of depository information into the specification do not involve new matter. Both aspects are fully permissible under the law. Moreover, the claim in the *Enzo* case referred specifically to “nucleotide sequences [are] selected from the group consisting of: a. The *Neisseria gonorrhoeae* [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof . . .”. The *Enzo* court specifically sanctioned this claim referencing sequences in a deposit which sequences are not otherwise disclosed in the patent

specification.

Application of the Law to the Instant Facts

Applicants have in essence taken the same legally accepted procedure to establish enablement and written description for the current claims even if it were true that the specification did not otherwise provide enablement and written description. As in *Lundak*, applicants have made a deposit after the filing date and inserted depository information into the specification, all without adding any new matter. As in *Enzo*, applicants are claiming a biological material by reference to the sequence information in the deposit, which sequence information is not otherwise present in the patent specification. Thus, the current claim set is fully enabled and has a written description.

One difference between *Lundak/Enzo* and the situation here is that, rather than no sequence information whatsoever being contained in the original application, there instead was incorrect sequence information originally disclosed. The examiner has not explained why this difference would prevent applicability of this law. The same purpose is achieved by the deposit and the claim language here as is achieved in *Lundak* and *Enzo*. The biological material clearly in the possession of the inventors before the filing date (see the accompanying Neri declaration¹ and his prior Statement) is being claimed, based on a patent specification which, as in *Lundak*, has examples describing “mutagenesis” procedures characterized by “uncertainties of reproducibility that inhere in such processes.”, at 773 F.2d 1218. In *Lundak*, no effort was made to provide sequence information. Here, an effort was made to provide sequence information which may have alleviated uncertainty, but that effort inadvertently involved errors. As a result, what remains is the same situation as in *Lundak* and *Enzo*: (a) a procedure is described which is inherently characterized by uncertainties of reproducibility; and (b) claimed subject matter recites sequence information not found in the original specification. In *Lundak*, a skilled worker carrying out the described process would have been able without undue experimentation to prepare at least a cell line equivalent to the specific one claimed. Here, following the procedures of the specification, a skilled worker would be able to prepare without undue experimentation an

¹ The new Neri declaration is captioned for related application 10/321,558 and is being filed therein on even date. Examples 1 and 2 of ‘558 are the same as Examples 1 and 2 of the instant application.

antibody at least having equivalent specificity and affinity to those of L19, irrespective of the erroneous sequence information given. (Neri declaration Paragraphs 8 and 9.) Thus, the sanctioned procedures of *Lundak* and *Enzo* are fully applicable here. Consequently, the claims are fully supported under 35 U.S.C. § 112.

The Examiner's Comments

As previously stated by applicant, the errors made in describing the sequence of actual antibody L19 regard 2 additional amino acids in the linker portion and an incorrect amino acid described for the VL region. As the examiner notes, these errors consistently were also carried over into other public disclosures of the sequence of the actual L19 antibody, e.g., as in the EMBL database mentioned by the examiner, etc. The examiner also accurately describes the fact that the now ATCC-deposited biological material contains a DNA sequence different from the sequence disclosed in this application. As noted herein, and as now even further elucidated in the Neri declaration being filed herewith, the deposited material contains a DNA sequence which is the same as the DNA sequence of the actually possessed L-19 antibody which was prepared before the filing date of the earliest ancestor application (May 11, 1998).

As the examiner also notes on page 12 of the office action, nothing in the originally filed specification accurately describes the post-filing date ATCC-deposited antibody coding sequence. But this is not the salient question. The pertinent question, it is respectfully submitted, is whether the current specification supports the current claims and whether the procedures used to arrive at the current specification are proper under the law. As indicated above, these procedures (the deposit of biological material having a DNA sequence which is the same as the actually possessed sequence of L19 prepared prior to the original filing date, and insertion of the corresponding depository information) are proper. Federal Circuit law is unambiguous as to their propriety. Consequently, the current specification properly supports the current claims under 35 U.S.C. § 112.

In the two last full paragraphs on page 13 of the office action, the examiner raises the issue of the inconsistency of example 2 as compared to the deposited material. In particular, the examiner notes that a skilled worker following Example 2 would arrive at an antibody having a 14aa linker and not a 12aa linker as in the deposited material.

Firstly, as the new Neri declaration clarifies, the references to Example 2 in Neri's first Statement inform that the procedures of the examples reflected the actual procedures utilized to prepare the actual L19 antibody prior to the filing date. See Neri declaration, Paragraph 10. The fact that incorrect sequence information was given for the linker length and one amino acid of the VL region does not affect the sufficiency of the procedures of Examples 1 and 2 to enable a skilled worker to arrive at L19 or a functionally equivalent antibody in specificity and affinity. See the Neri Declaration, Paragraphs 8 and 9.

Secondly, the claims do not rely on Example 2 for either enablement or written description for reasons fully discussed above and as fully proper under *Lundak* and *Enzo*, as discussed above. Thus, the points made by the examiner on pages 13 and 14 do not justify any continued rejections.

For the foregoing reasons, the addition of the deposit information and the deposit itself to the specification is not new matter. *Enzo* and *Lundak*. The "new" sequence is properly provided by the deposit. Similarly, deletion of the original sequence information is not new matter since it does not add any new substantive subject matter to the application. Moreover, its deletion is irrelevant since the claims reference only this deposit.

Double Patenting

Appreciation is expressed to the examiner for pointing out on pages 15 and 16 the inconsistency between this application and 10/321,558. The amendment to the latter being filed herewith removes this unintended problem. The filing date of 10/204,581 is March 10, 2003. This is later than the effective filing date of the current application which is May 11, 1998. Accordingly, this application must be permitted to issue without any double patenting rejection made in view of the later application under MPEP § 804(I)(B)(1). Moreover, '581 has recently been amended in a fashion which also renders the rejection moot.

Respectfully submitted,

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